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Work package 5 – Task 5.1

Report on interoperability of IIS in the EU area

(Deliverable 5.2)

Report prepared by

Tamara Buble

Division for Health Informatics and Biostatistics

Croatian Institute of Public Health

Rockefellerova 7, 10000 Zagreb

Croatia

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Abbreviations

CDC	Centres for Disease Control and Prevention
ECDC	European Centre for Disease Prevention and Control
EIF	European Interoperability Framework
EIR	Electronic Immunisation Records
EU-JAV	EU Joint Action on Vaccination
HaDEA	European Health and Digital Executive Agency
ICT	Information and Communication Technology
IIS	Immunisation Information Systems
MoH	Ministry of Health
NHIO	National Health Insurance Organisation
NIPH	National Institute of Public Health
RHA	Regional health Authorities
UID	Unique Identifier
WP	Work Package

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Executive summary

Immunization information systems (IIS) assist in recording, monitoring and assessing vaccination programmes in public health systems. In the present WP5 report, we wanted to: 1) obtain up-to-date information about the status of IIS implementation in the EU area; 2) obtain up-to-date information on the data quality and data collection processes; 3) assess the compliance of existing IIS to the new European Interoperability Framework (EIF).

The main method of gathering data was a questionnaire sent to 20 European countries in summer of 2019. To update the data, in February 2022 we repeated 2019 questionnaire, with the addition of questions on the compliance with EIF. 17 countries responded on the status of IIS implementation: Austria, Belgium (Flanders), Bulgaria, Croatia, Denmark, France, Finland, Greece, Italy, Latvia, Lithuania, Netherlands, Norway, Slovakia, Slovenia, Spain and Sweden.

Out of 17 countries, 10 countries have IIS implemented (8 national, 2 regional), 2 national IIS are in pilot phase and 5 countries reported not having an IIS.

We observed that the key elements for building an IIS exist either partially or fully in all countries. This foundational architecture consists of: A) complete and accurate population denominators such as population registry or the closest approximation (e.g., national statistics office estimates, national health insurance registries); B) unique identification of immunisation recipients (via uniform unique identifiers - UID); C) vaccinations and vaccine details records (batch and vial ID etc.) given to the recipients (including the dates of doses).

While fully digitalised timely data collection made possible via IIS accelerates its use for public health, collecting data timely remains a problem for countries without IIS.

Many countries face a variety of barriers for developing IIS and for improving international data exchange and sharing. Legislations of the mandatory data collection on vaccination and funding issues stand out as such. In most countries with an IIS, there is fully or partially established governance over interoperability processes, as well as governance and ownership over IIS, with high-level political support existing in most countries. As part of the semantic and technical interoperability, all the countries have agreed on the specification on the data to be collected and format standards, and international standards are widely used.

The study indicated that there are significant foundational elements in place in most national public health systems for the data sharing and exchange to be established among the countries' immunisation systems. The COVID-19 pandemic has accelerated the development of IIS and demonstrated that many if not all of the barriers indicated by the stakeholders in this study can be overcome with the sufficient political and public support.

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Introduction

The main objective of the Work package 5 (WP5) of the EU Joint Action on Vaccination (EU-JAV) is to strengthen the interaction of immunisation information systems (IIS) in Europe in order to increase vaccine surveillance capabilities and to increase vaccination coverage. In particular, the aim of the Task 5.1. was to assess the interoperability of European IIS and opportunities for standardisation.

Immunization information systems (IIS) are defined by US CDC as "*confidential, population-based, computerized databases that record all immunization doses administered by participating providers to persons residing within a given geopolitical area. At the point of clinical care, an IIS can provide consolidated immunization histories for use by a vaccination provider in determining appropriate client vaccinations. At the population level, an IIS provides aggregate data on vaccinations for use in surveillance and program operations, and in guiding public health action with the goals of improving vaccination rates and reducing vaccine-preventable disease*" (1).

IIS are important for monitoring the vaccine coverage, identifying the population at risk and points for intervention, and assessing the performance of vaccination programmes. They are of tremendous assistance for providing the information for immunisation policies and strategies and related health initiatives that can lead to improving vaccination rates and reducing vaccine-preventable disease (2,3). Additionally, ECDC pointed out the role that the adoption of the IIS and their integration in health systems plays in both European Council and WHO policies (2).

Recognising the relevance and the importance of IIS for the support of vaccination programmes, ECDC outlines six important features required for IIS to support the vaccination programmes (2):

1) Complete and accurate denominator populations from different sources;
2) Secure vaccine recipient and record identification through uniform unique identifiers (UID);
3) Complete, timely and correct vaccination records with real-time electronic access to the IIS;
4) Vaccinations records and vaccine details records (batch and vial ID etc.) given to the recipient, facilitated by pre-entered information, selection menus and reading of barcodes;
5) Production of automated outputs;
6) The facility to offer services that are useful to all parties, including vaccine recipients, parents and vaccine providers. For example, recall functions, trusted medical information, and the possibility for parents and vaccine recipients to request certified records of immunisation history.

Furthermore, it would be beneficial for an IIS to be capable of exchanging data with other national IIS. This ability to exchange systematically defined information through semi or fully automated systems is what we understand as interoperability. However, the interoperability challenge is not only technological. It is also a matter of organizational management, business procedures, data

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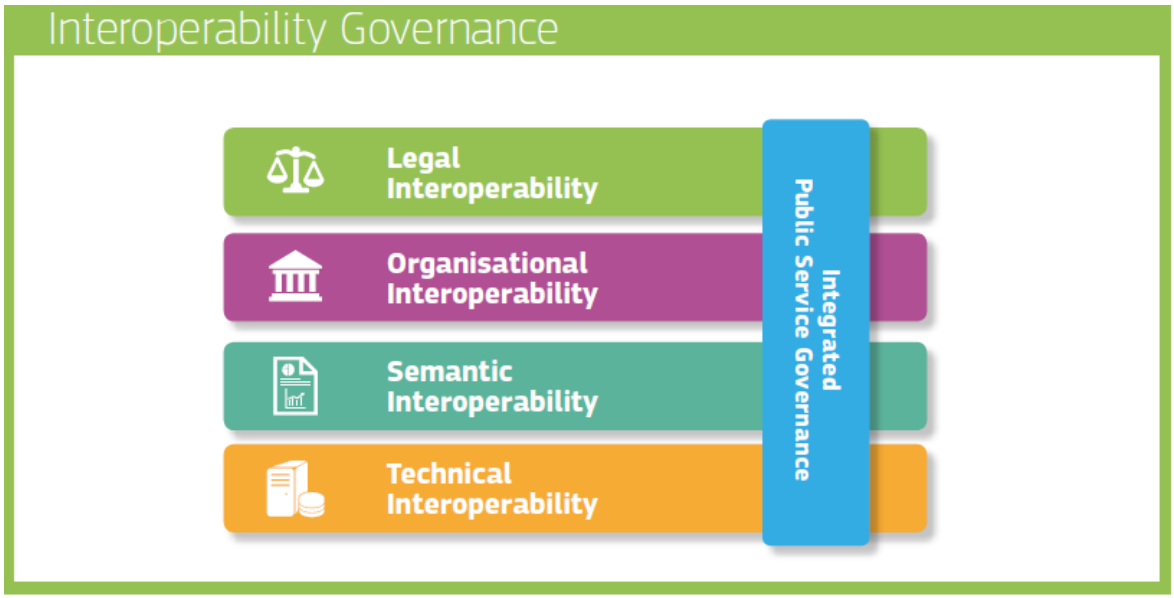
management and data governance, along with the issues pertaining to structural constraints of top-down and bottom-up models of several interconnected layers.

For the purpose of our work in the EU-JAV, we relied on the new European Interoperability Framework (EIF) definition of the interoperability as "*the ability of organisation to interact towards mutually beneficial goals, involving the sharing of information and knowledge between these organisations, through the business processes they support, by means of the exchange of data between their information and communication technology (ICT) system*s" (4). EIF proposes an interoperability model composed of four layers of interoperability – legal, organisational, semantic and technical; a cross-cutting component of the four layers, 'integrated public service governance'; and a background layer, 'interoperability governance' and of 12 underlying principles. The model, which we decided to follow in operationalizing the interoperability of the IIS is depicted in Figure 1.

Figure 1 EIF's Interoperability Model



As shown above, several layers of interoperability need to be considered in the model:

The interoperability governance, as proposed by EIF, is the backbone of the interoperability model. It precedes and overarches the work on interoperability as it defines decision-making, organisational structures, ownership, roles, responsibilities and other aspects required for ensuring interoperability.

Respecting legal and regulatory frameworks existing on various geographic levels (national, subnational), and problem matter levels (domain-specific) presents a formidable challenge for setting up data exchange. Legal interoperability is the ability of organisations regulated within different legal frameworks to cooperate. Successful addressing legal interoperability is the key for facilitating interoperability at lower layers of interoperability.

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Organisational interoperability consists of aligning business procedures and ensuring coordination on the level of organisations involved in the entire process, and especially those involved directly into data sharing and exchange.

Once regulatory frameworks are in sync and business procedures aligned, semantic interoperability ensures the common understanding of the meaning of the names, structures, classifications and everything else required in the data exchanged. A key step towards addressing semantic interoperability is adopting common data formats, classification and vocabulary standards that help to identify, categorize and explain the meaning without ambiguities.

Technical layer of interoperability ensures the technical prerequisites for sharing and exchanging data – such as "*interface specifications, interconnection services, data integration services, data presentation and exchange, and secure communication protocols*" (EIF) (4).

Finally, integrated public service governance, a cross-cutting component of the EIF's interoperability model is the component common to each of the four main layers: legal, organisation, semantic and technical. Integrated public service governance enables the coordination necessary for ensuring users' needs are identified and met. The process occurs through continuous integration and improvement of services, quality cycles, change management and recovery plans.

Within the scope of this Task, our goal was to achieve the following:

1) Obtain up-to-date information about the status of IIS implementation in the EU area.
2) Obtain up-to-date information on the data quality and data collection processes.
3) Asses the compliance of existing IIS to the European Interoperability Framework.

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Methods

Two surveys were developed and distributed to 20 countries.

The first one, launched in 2019, aimed to assess the information of the status of implementation of the IIS, the data quality and data collection processes. The questionnaire for this survey was partially adapted from ECDC survey conducted in 2016 (2) in order to obtain updates on the matter. The survey was conducted again in 2022 in a concise form due to the pandemic and therefore the outdate data, asking whether anything has changed since 2019.

The second survey was conducted in 2022 along with the repeated 2019 survey (surveys were bundled together), with the aim of assessing the compliance of both the existing IIS in piloting phase with EIF. Previously mentioned interoperability layers were taken as a basis for the development of this survey, complementing the questions from the 2019 survey with open-ended questions emanating from the research on interoperability for public health policy conducted within the "Information for Action" Joint Action (InfAct) project (5). In particular, within the WP10 of InfAct project, we had previously explored how various projects and initiatives deal with cross-border health data exchange in Europe, and assessed enablers and barriers for the interoperability. Some of these answers served as a basis for our questionnaire.

Both questionnaires are available in the Appendices.

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Results

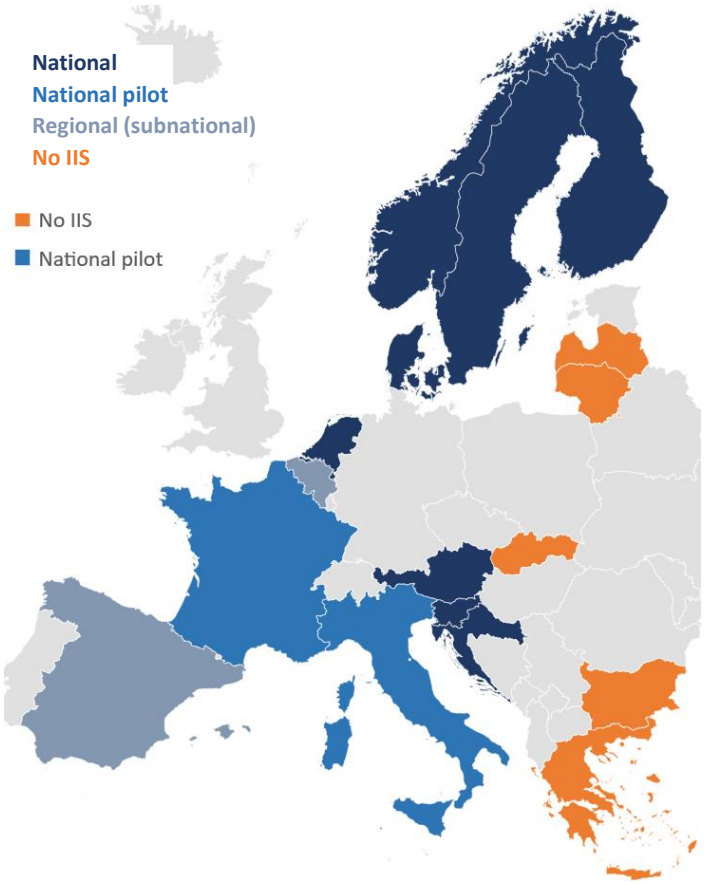
IIS implementation status, data quality and data collection processes

In total, we obtained information from 17 countries on the status of IIS implementation. 16 countries responded to the initial questionnaire (June-September 2019): Belgium (Flanders), Bulgaria, Croatia, Denmark, France, Finland, Greece, Italy, Latvia, Lithuania, Netherlands, Norway, Slovakia, Slovenia, Spain and Sweden. In March 2022, 10 countries have updated us on their IIS development since 2019: Austria, Belgium (Flanders), Croatia, Denmark, Finland, France, Norway, Slovenia, Spain and Sweden. Out of these 10 countries, 4 have reported significant changes in their IIS development and updated their answers from 2019 survey (Austria, Belgium, Croatia and Sweden). Part of the report is based on updated questionnaire from 2022, while for the 6 countries which didn't report an update on their IIS (Bulgaria, Greece, Italy, Latvia, Lithuania, Netherlands and Slovakia) are reported on using the information collected in 2019.

IIS implementation status, level and governance

Out of 17 countries, 10 countries have IIS implemented (8 national, 2 regional), 2 national IIS are in pilot phase, and 5 countries reported not having an IIS. The status of IIS implementation is given in the Chart 1.

Chart 1 An overview of IIS implementation status



Out of the 10 countries that have functional IIS, 7 reported their IIS definition is fully aligned with the CDC definition of IIS (Austria, Belgium (Flanders), Croatia, Denmark, the Netherlands, Norway and Slovenia); while 3 (Finland, Spain and Sweden) provide aggregate data at population level only. Out of IIS in piloting, Italy reported their IIS definition fully fits the CDC definition, while France reported it that the current legislative regarding IIS does not allow health authorities or public health agencies to collect these for epidemiological purpose – a problem that could be solved by the new regulation once the IIS implementation takes place.

Governance, defined as the "*body at national or regional (subnational) level that is in charge of the day-to-day management of the IIS and of the data*

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contained in the system" (2), is the sole responsibility of a single institution in 6 countries. More precisely, it is the national institute of public health (or equivalent) in 5 countries (Denmark, Finland, Norway, Slovenia, and Sweden), Ministry of Health in 1 country (Spain), and regional health authorities in 1 country (Flemish part of Belgium), while 5 countries reported the governance over their IIS is shared among institutions (Austria, Croatia, France, Italy and the Netherlands). The respondent answers are given in Table 1.

Table 1 IIS implementation status, level and governance (N=17)

Country	IIS in place	Year of establishment	IIS level	Alignment with CDC definition	Governance*	Reported significant changes since 2019
Austria	Yes	2020	National	Yes	MoH, RHA, NHIO	Yes
Belgium (Flanders)	Yes	2006	Regional	Yes	RHA	Yes
Bulgaria	No[1]	-	-		-	-
Croatia	Yes	2020	National	Yes	NIPH, MoH, NHIO	Yes
Denmark	Yes	2013	National	Yes	NIPH	No
Finland	Yes	2009	National	No	NIPH	No
France	National IIS in piloting	N/A	National	No	NIPH, MoH, NHIO	No
Greece	No[1]	-	-		-	-
Italy	National IIS in piloting[1]	2020 (plan)	-	Yes	MoH, RHA	-
Latvia	No[1]	-	-		-	-
Lithuania	No[1]	-	-		-	-
Netherlands	Yes[1]	2005	National	Yes	NIPH, MoH	-
Norway	Yes	1995	National	Yes	NIPH	No
Slovakia	No[1]	-	-		-	-
Slovenia	Yes	2017	National	Yes	NIPH	No
Spain	Yes	2020	Regional	No	MoH	No
Sweden	Yes	2013	National	No	NIPH	Yes

[1] Data from Greece, Italy, Latvia, Lithuania, the Netherlands and Slovakia is from 2019 survey.

* NIPH – National Institute of Public Health (or equivalent)
MoH – Ministry of Health
RHA – Regional Health Authorities
NHIO – National Health Insurance Organisation

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Specific country context

National IIS in piloting

Italy: All Regions and Autonomous Provinces have their own IIS. The 2 Italian Autonomous Provinces are moving to a different IIS and this is why they are not included in the description. The regional IIS are not able to share their data but the national one makes it possible as it operates as bridge.

France:
France has different systems:

- A national data health system that is a reimbursement database used to estimate vaccine coverage. This database is national.
- A vaccine card integrated in the shared medical file (Dossier medical partagé) of the person. It is national and pilot IIS, supported by Ministry of Health. This vaccine card and the shared medical file will be integrated in 2022, in a new digital health card (mon espace sante) that will be created for each citizen. This digital health card is interoperable with the majority of the health professional's software.

Another system is an electronic immunisation record platform developed mainly in two regions (Auvergne-Rhône-Alpes and Nouvelle Aquitaine): this IIS is called MesVaccins.net. It is regional and private, and not operated by the Ministry of Health (although its use is officially encouraged). MesVaccins.net integrates an expert system that is real-time updated by vaccinology professionals.
The answers in this survey regard to MesVaccins.net, unless noted otherwise.

Regional/Subnational IIS

Belgium: The responsibility for vaccination is subnational. Belgium has two IIS in place: Vaccinnet covers Flanders region and parts of Brussels, in Flemish language. e-Vax is a similar system for the Walloon Region and parts of Brussels, in French language. Two systems have similar structures, characteristics and data elements and data can be shared among systems. Walloon system has same database system as Flemish one, but less new possibilities (only web-based). For Covid-19 vaccinations, the whole country uses Vaccinnet which is the reference source for Covid-19 vaccination data and for elaborating the vaccination certificates for Digital Covid Certificate (DCC). Initially, Vaccinet was covering approximately 7 million people, but it was broadened for for registration of Covid-19 vaccinations to 11 million people. e-Vax is covering approximately 5 million people. The answers in this survey regard to Vaccinet IIS, unless noted otherwise.

Spain: Spain has decentralised system with different structure and characteristics (8 IIS and 11 electronic registries), and the data sharing between them is not possible. There are 17 regions and 2 autonomous cities in Spain, and each one is responsible for public health on its territory. However, the national objectives and basic directives are established and overseen by the Health Ministry of Spain in cooperation with the regions. Each region and autonomous cities have their own IIS or Electronic

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Immunisation Records (EIR). They are not interconnected. All of them report at national level, thanks to a common agreement on indicators. At national level an IIS is being developed (2019). Since the specific IIS for COVID-19 vaccination coverage (REGVACU) was launched at the end of 2020, there has been an increasing willingness from different stakeholders to develop a national IIS for vaccine coverage of the vaccines included in the routine immunisation schedule of Spain. The project was launched in February 2022 and it is currently at a very early stage. The national IIS is going to be as similar as possible to REGVACU therefore users will already be used to the IIS.

Countries with functional IIS and IIS in pilot phase

Vaccine legislation and IIS vaccination records

Seven (7) countries reported that both public and private vaccination providers are required by law or regulations to record individual vaccinations in the IIS (Austria, Belgium/Flanders, Croatia, Denmark, Norway, Slovenia and Sweden). In 2 countries (Finland and Italy) mandatory recording of individual vaccinations applies only to public providers. In Finland, private providers are required to record vaccine information, but the record submission to their IIS is not required. In Italy, private providers are not required to record vaccinations but they are required to provide citizens with specific documentation that can be registered in the IIS through public services. Three countries (France, the Netherlands and Spain) reported the absence of legal requirements for providers to record vaccination information.

When asked which vaccines are legally required to be registered, 6 countries have reported all vaccinations are legally required (Croatia, Denmark, Finland, Italy, Norway and Slovenia), while in 3 countries only some vaccinations are legally required to be registered. There is no information from France and Italy, and the answer from Spain is N/A.

The answers are presented in Table 2.

Table 2 Vaccine legislation and IIS (N = 12)

Country	Legislation to record individual vaccinations in the IIS	Which provided vaccinations registration is required by the law	Which provided vaccinations are recorded in IIS
Austria	Public and private providers	Influenza and COVID-19	All vaccinations
Belgium (Flanders)	Public and private providers	Childhood Vaccination programme and other Vaccination programme (adults) + COVID-19 vaccines	All vaccinations
Croatia	Public and private providers	All vaccinations	IIS provides COVID-19 vaccination records, for other immunisations it is still upgrading
Denmark	Public and private providers	All vaccinations	All vaccinations

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Country	Legislation to record individual vaccinations in the IIS	Which provided vaccinations registration is required by the law	Which provided vaccinations are recorded in IIS
Finland	Public providers	All vaccinations	All vaccinations
France	No legislation	-	Childhood and Adolescent vaccinations; All vaccinations in system being piloted[1]
Italy	Public providers	All vaccinations	-
Netherlands	No legislation	-	Childhood Vaccination programme and Adolescent Vaccination programme
Norway	Public and private providers	All vaccinations	All vaccinations
Slovenia	Public and private providers	All vaccinations	All vaccinations
Spain	No legislation	N/A	N/A
Sweden	Public and private providers	Childhood Vaccination programme + COVID-19	Childhood Vaccination programme and Adolescent Vaccination programme

[1] France: childhood and adolescent vaccinations are recorded in National Data Health System from which the vaccine coverages are estimated, not in a national IIS. The IIS in pilot phase is recording all vaccinations provided.

Identification of records

In all the countries except Spain, a personal identifier is used in IIS for identifying vaccinated persons. Most common unique identifier is the personal number given to citizen at birth or immigration: it is used alone (6 countries) or in combination with other unique identifiers (2 countries). In Austria, the IIS uses unique identifier used for healthcare services, while in the Netherlands, citizen service number is used as a unique identifier.

Regarding the identification of vaccine administered, most of the countries use a combination of several possibilities. The most common way of identifying the vaccine is selection from a list (8 countries), followed by manual entry (7 countries). Three (3) countries have additional electronical recording through the barcode reader, or/and linking to the product database.

To record vaccinations into IIS, countries use a combination of options: 10 countries use the local coding, 9 countries use the identification through the batch/lot number, 9 countries use the trade name, 6 countries use the antigen and 5 countries use the ACT classification. Two countries (France and Slovenia) reported additional ways of recording vaccinations in IIS. Most of the countries use a combination of three items or more.

Regarding the responsibility of the vaccine coding system implemented nationally, in 7 countries it is the sole responsibility of a single institution, most commonly the national institute of public health or country/regional medicinal authority. Belgium, Croatia and France reported multitude of agencies responsible for coding system.

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An overview of system characteristics is given in Table 3.

Table 3 Population coverage and identification and recording of vaccinations (N=12)

Country	Unique identifier (UID) for use in IIS	How is the data that identifies the vaccine administered recorded	How are vaccinations recorded in IIS?	Who is responsible for the coding system?
Austria	UID used for healthcare services	• Manually • Electronically with the help of a barcode reader • Selecting from a list of vaccines included in the registry • Linking to a product database	• By trade name • Local coding • Batch/lot number • ATC classification • Antigen	• ELGA Gmbh (national e-health agency)
Belgium (Flanders)	UID given to citizens at birth or immigration	• Selecting from a list of vaccines included in the registry • Upload from electronical medical files by webservice	• By trade name • Local coding • Batch/lot number • ATC classification	• Country medicinal authority • Regional medicinal authority
Croatia	UID given to citizens at birth or immigration + UID for healthcare services	• Manually	• By trade name • Local coding • Batch/lot number • ATC classification	• Country medicinal authority • Health Insurance Fund • Public Health Institution
Denmark	UID given to citizens at birth or immigration	• Selecting from a list of vaccines included in the registry	• By trade name • Local coding • Batch/lot number • ATC classification • Antigen	• Public Health Institution
France	UID given to citizens at birth or immigration	• Electronically with the help of a barcode reader • Linking to a product database	• Local coding • ATC classification • Code CIP (Code identifiant de présentation)	• Country medicinal authority • Expert system provider
Finland	UID given to citizens at birth or immigration	• Manually • Selecting from a list of vaccines included in the registry • Linking to a product database	• By trade name • Local coding • Batch/lot number • Antigen	• Public Health Institution
Italy*	UID given to citizens at birth or immigration	• Selecting from a list of vaccines included in the registry	• By trade name • Local coding • Antigen	• Country medicinal authority
Netherlands	Citizen service number	• Manually	• Local coding • Batch/lot number • Antigen	• NCJ (Dutch Centre for Youth Health Care)

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Country	Unique identifier (UID) for use in IIS	How is the data that identifies the vaccine administered recorded	How are vaccinations recorded in IIS?	Who is responsible for the coding system?
		• Electronically with the help of a barcode reader • Selecting from a list of vaccines included in the registry • Exchange with other EHR		
Norway	UID given to citizens at birth or immigration	• Manually • Selecting from a list of vaccines included in the registry • Electronically by using electronic patient record systems • csv file imports	• Local coding (mandatory) • By trade name (not mandatory) • Batch/lot number (not mandatory)	• Public Health Institution
Slovenia	UID given to citizens at birth or immigration + UID for healthcare services	• Selecting from a list of vaccines included in the registry	• By trade name • Batch/lot number • SNOMED CT	• Public Health Institution
Spain	N/A	• N/A	• N/A	• N/A
Sweden	UID given to citizens at birth or immigration	• Manually • Selecting from a list of vaccines included in the registry	• By trade name • Local coding • Batch/lot number • Antigen	• Country medicinal authority

* Information related to the IIS in piloting.

IIS: Linkage, inputs and timely data collection

This section covers the linkage with population registries, and timely data collection.

Seven (7) IIS systems are linked with the population registries or healthcare population registries. In other countries, the data is entered manually at the time of person's encounter for immunisation.

When it comes to the estimation of time between vaccination and the information being entered in the IIS, it varies from one day to one week.

Eight (8) countries can record vaccinations administered in the past. The same 8 countries have a facility for recording vaccinations administered in a foreign country. In the country with subnational IIS (Belgium), it is possible to record vaccinations administered in another region.

The overview of respondents' answers is given in the Table 4.

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Table 4 Linkage with population registries and timely data collection (N=12)

Country	Linkage with population registry	Estimated time between vaccination and recording in IIS	Vaccinations administered in the past can be recorded	Vaccinations administered in a foreign country or another region can be recorded
Austria	-	-	Yes	Yes
Belgium (Flanders)	Yes, by civil population registries	Depends on the vaccinator: at the moment of vaccination of later	Yes	Yes
Croatia	Data are entered manually only at time of a person encounter for immunisation	Within 1 day	Yes	Yes
Denmark	Yes, by civil population registries	Within 1 week (7 days)	Yes	Yes
Finland	Yes, by civil population registries	Within 1 day	Yes	Yes
France	Yes, by healthcare population registries	Real-time*	No*	No*
Italy	N/A	All vaccinations	Yes*	Yes*
Netherlands	Yes, by civil population registries	Vaccinations given by healthcare providers within 1 day; but vaccinations given abroad can be registered after several years. And everything in between.	Yes	Yes
Norway[1]	Yes, by civil population registries	Within 1 week (7 days)	Yes	Yes
Slovenia	Yes, by civil population registries	Within 1 day	No	No
Spain	N/A	N/A	No	No
Sweden	Data are entered manually only at time of a person encounter for immunisation	Within 1 day	No	No

* Information related to the IIS in piloting.

[1] Norway: The time between vaccination and the information being entered into the IIS is defined in the SYSVAK registry regulation. However, this is affected by a number of factors such as technical Reporting issues, and delay in manual operations (some does not report electronically to SYSVAK. They send registrations by mail to the NIPH for manual registration).

IIS: Minimal set of data variables

The minimal set of data variables to be recorded for an immunisation record to be valid by country is listed in the Table 5. In addition, all countries require unique identifier of the immunised person, as noted before. Common set of variables for all countries consist of person unique identifier (UID), as

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noted before, vaccine identification and date of vaccination. Additional set consists of vaccination doses and health care provider information. The overview of the answers is given in a Table 6.

Table 5 Minimal set of data variables for a record to be valid (N=12)

Country	Minimal set of data variables to be recorded
Austria	• vaccine (name/code+lot) • dose number (Immunization Schedule Entry) • immunization target • author
Belgium (Flanders)	• automatically: look for the person being vaccinated (is in the database), add date of vaccination, choose vaccine (brand or generic) • data of the vaccinator are linked to the dataset • group registrations are possible for a same vaccine (brand) on the same day and with the same batch number
Croatia	• unique personal IDs, first and second name, date of birth • vaccine attributes (type, ATC code, local code, name, serial number, expiration date), immunization dose • date of administration, facility of administration (unique ID and name) • medical doctor that administered (unique ID, first and second name)
Denmark	• identification of the vaccinee • the Unique identifier of the patient • date of vaccination • vaccine and batch number
France	• N/A
Finland	• date • organization • name of professional • vaccinee ID • generic name • trade name (can be omitted if only generic name known) • batch number (can be omitted if only trade name known) • package identification number called “VNR” (can be omitted) • site of administration (can be omitted) • route of administration (can be omitted)

Italy*	• Mandatory Personal data
	  ◦ Patient ID
	  ◦ gender
	  ◦ Date of birth
	  ◦ City of residence
	  ◦ Local Health Unit (LHU) of residence
	  ◦ Region of residence
	  ◦ State of Residence
	  ◦ Nationality
	• Mandatory Vaccinations
	  ◦ Patient ID
	  ◦ Vaccine administered Dispenser Type
	  ◦ AIC Code (Marketing Authorization) - National identification code of the vaccine
	  ◦ Vaccine Denomination
	  ◦ Formulation type
	  ◦ Route of administration

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	• Lot number • Expiration date • Administration Date • Inoculation site • City of vaccine administration • LHU of vaccine administration • Region of vaccine administration • Foreign State of vaccine administration • Vaccine content Antigen • Dose
Netherlands	• vaccination date • antigen type (e.g., MMR, DTaP-IPV)
Norway	• name • personal ID number • address • date of vaccination • contraindication (medical or other) • vaccination code (SYSVAK code) • registration date • reporting unit
Slovenia	• unique identifier used for mandatory health insurance • citizens number • date of vaccination • vaccine • dose • indication for vaccination • site of application of vaccine • route of application of vaccine
Spain	• N/A
Sweden	• personal identifier • vaccine • date of vaccination • health care provider

* Information related to the IIS in piloting.

Countries with no IIS

System characteristics

As previously mentioned, all of the countries that returned the questionnaire in 2019 and that did not have IIS have not filled the updated 2022 questionnaire. This part of the report is exclusively about such countries, as all of the countries that did return the 2022 questionnaire do have either an operational or pilot-phase IIS.

An overview of the model of reporting vaccinations, frequency of receiving administrative data, information on data for vaccination and population denominator is given in a table below.

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Table 6 Countries with no IIS: model of reporting vaccinations, frequencies, data and coverage estimation denominator

Country	Model of reporting vaccinations	Frequency of receiving administrative data	Data for vaccination	Denominator
Bulgaria	• Sub-national with sharing on national level	• Quarterly at the regional level; twice a year at the national level	• Doses	• Civil population registries • Healthcare population registries
Greece	• No structured administrative reporting system in place. Vaccine coverage estimations are performed by national population-based surveys, with data derived from child health booklets, from specific cohorts.	• N/A (there is no administrative data receival)	• Type of vaccination by general name • Doses	• Population estimation made by relevant authority (statistics bureau or equivalent)
Latvia	• Sub-national with sharing on national level	• Monthly	• Type of vaccination by general name • Doses • ATC codes	• Population estimation made by relevant authority (statistics bureau or equivalent)
Lithuania	• National	• Monthly	• disease, age	• Healthcare population registries • Population estimation made by relevant authority (statistics bureau or equivalent)
Slovakia	• Data are collected by public health workers based on paediatricians´ documentation annually, not reported by HCW	• Annually	• data are not reported only registered in documentation; they include name of vaccine, dose, batch number, date of administration	• Healthcare population registries

IIS implementation barriers

For the countries with no IIS, we assessed their IIS planning and implementation barriers. Lack of funding has been recognized as the main barrier in all of such countries. The lack of human resources has also been recognised by all, apart from Lithuania. The two recognised barriers are legislation and governance, both of which need to be solved in an early stage of setting an IIS. An exception to all the countries seems to be Lithuania, who recognizes lack of funding as the only barrier. In other words, judging by the questionnaire alone, all that Lithuania requires to start implementing their IIS is funding.

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On the other side of spectrum are Greece and Latvia, which find that most of the barriers offered in the questionnaire apply to them. The strangest case of all, perhaps apart from the mentioned Lithuanian case of lacking funding and funding only, seems to be Slovakia, where every single one of the offered barriers is deemed to be somewhat a barrier.

IIS implementation barriers	Bulgaria	Greece	Latvia	Lithuania	Slovakia
Lack of funding	Yes	Yes	Yes	Yes	Somewhat
Lack of human resources	Yes	Somewhat	Yes	No	Somewhat
Need to vote a legislation to govern the use of the IIS	No	Yes	Yes	No	Somewhat
Need to establish governance and ownership (defining who was in charge of responsibility of the system)	No	Yes	Yes	No	Somewhat
Data protection issues	Somewhat	No	Somewhat	No	Somewhat
Definition of users and stakeholders to be involved	No	Yes	Somewhat	No	Somewhat
Decentralisation of immunisation programmes	No	No	No	No	Somewhat
Lack of efficient infrastructure that could support the IIS (e.g., lack of computer or Internet connection at the local level)	Somewhat	Somewhat	Somewhat	No	Somewhat
Lack of standards as point of reference for developing the system	No	Yes	Yes	No	Somewhat
Defining rules for access rights to different users (national agency, local health officers, health providers…)	No	Somewhat	No	No	Somewhat
Low information literacy	No	Somewhat	Yes	No	Somewhat

Additional information on IIS development status:

Greece: The establishment of an electronic prescription (e-prescription) database in 2012, which includes vaccine prescription data, instigated the first effort to develop a national vaccine registry. The National Vaccination Committee created a working group that attempted to use, in a pilot study, the available e-prescription data, in order to design an administrative method for the estimation of vaccine coverage. Recently, in June 2019, the Ministry of Health formulated a working group dedicated to the development of a National Vaccine Registry with the participation of different competent bodies and stakeholders.

Slovakia: We are preparing conditions for developing a system within next 2-3 years (up to 2022).

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IIS compliance with European Interoperability Framework

Survey on the compliance of the national IIS with the EIF was sent to 20 countries in February 2022, 10 of which have responded (Austria, Belgium, Croatia, Denmark, Finland, France, Norway, Slovenia, Spain and Sweden).

Governance of IIS interoperability at a national level

A holistic governance of interoperability activities across administrative levels and sectors regarding IIS (such as frameworks, institutional arrangements, organisational structures etc.) is fully ensured in 5 and partially in 4 countries out of 10 countries that filled out this questionnaire. The exception is Belgium (Flanders part), who answered "N/A" to this question. Governance and ownership over IIS are fully agreed and established in 8, and partially in 2 countries.

The high-level political support (such as ministries) regarding IIS governance and use is an important component for cross-sectoral or cross-border interoperability. All 10 countries have responded that such a support exists in their countries, although 3 countries reported only a partially existing support. Another indicator of high-level support in countries is sustainability: continued financing of support and operations of the resources is fully ensured in 6 countries and partially in 3 countries, while financing and planning of future development of the resources is fully ensured in 2, partially in 7, and not ensured in one country.

The overview of the responses by country is given in the table below.

Table 7 IIS interoperability governance (N=10)

Country	Holistic governance of interoperability	Governance and ownership over IIS	High-level support	Continued financial and resources support	Future planning
Austria	Yes	Yes	Yes	Yes	Yes
Belgium (Flanders)	N/A	Yes	Yes	Yes	Yes
Croatia	Partially	Partially	Partially	Partially	Partially
Denmark	Yes	Yes	Yes	Yes	Partially
Finland	Partially	Yes	Partially	Yes	Partially
France	Partially	Yes	Partially	No	Partially
Norway	Yes	Yes	Yes	Yes	Partially
Slovenia	Yes	Yes	Yes	Yes	No
Spain	Yes	Partially	Yes	Partially	Partially
Sweden	Partially	Yes	Yes	Partially	Partially

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Legal interoperability

"Digital check" of proposed legal framework regarding IIS, according to EIF (4), consists of compliance with digital environment, removing digital exchange barriers and assessing ICT impact on stakeholders. Seven out of 10 countries reported that legislation regarding IIS fits both "physical" and "digital" worlds. Barriers to digital exchange were identified on the level of legislation in 3 countries, partially in 4 countries. This question was answered with N/A by two countries. Legislation was screened to identify and assess its ICT impact on stakeholders in 3 countries. However, this was answered with N/A by 4 countries, leading to the conclusion that legislation was not relevant or the question was not well understood. The respondent answers are given in the table below.

Table 8 legal interoperability - digital check (N=10)

Country	Compliance of legislation with digital environment	Barriers to digital exchange identified	ICT impact on stakeholders identified and assessed
Austria	Yes	N/A	Yes
Belgium (Flanders)	Yes	Partially	N/A
Croatia	No	No	No
Denmark	Yes	Yes	Yes
Finland	N/A	N/A	N/A
France	Yes	Yes	Yes
Norway	Yes	Partially	N/A
Slovenia	Yes	Yes	Partially
Spain	Partially	Partially	Partially
Sweden	Yes	Partially	N/A

We assessed the work on screening and adapting the existing legislative regarding the availability of data to users, access rights, and data exchange. The legislation regarding the availability of data from IIS is clear and easy to understand for 5 countries, partially for 3, and is unclear for 2 countries. Formal agreements that define the rights of different users exists in 5 countries, partially in 3. In one country there are no such agreements, and one country replied N/A to this question. Formal agreements that define data sharing between organisations exist in 6 countries, partially in 1. In one country there are no such agreements, and two countries replied N/A to this question. The answers are presented in the table below.

Table 9 legal interoperability - existing legislative (N=10)

Country	Legislation regarding the availability of data from IIS is clear and easy to understand.	Formal agreements that define users' access rights	Formal agreements that define data sharing between organisations
Austria	Yes	Yes	Yes

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Country	Legislation regarding the availability of data from IIS is clear and easy to understand.	Formal agreements that define users' access rights	Formal agreements that define data sharing between organisations
Belgium (Flanders)	Yes	Yes	Yes
Croatia	No	Partially	Partially
Denmark	No	Yes	Yes
Finland	Partially	Partially	N/A
France	Yes	Partially	Yes
Norway	Partially	Yes	Yes
Slovenia	Yes	Yes	Yes
Spain	Yes	No	No
Sweden	Partially	N/A	N/A

Organisational interoperability

Functions required by the systems are fully defined and implemented in 6, and partially in 4 countries. Integration and alignment of operational processes, that is, documenting whether stakeholders' management and work processes are convergent, in order to establish shared work procedures and define their role in delivering public service, are fully carried out in 3 countries, and partially in 7. When it comes to linkage with other population and health databases and registries, population register is fully integrated with IIS in 5 countries, partially in 3 and it is not integrated or N/A in 2 countries. The integration/linkage with health outcome registries and databases such as patient record databases, hospital discharges databases, communicable disease databases or pharmaco-vigilance registries is fully carried out in 3 countries, partially in 2 and is not carried out or in 5 countries. It is similar when it comes to integration with another databases (such as vaccine information).

The IT infrastructure that supports IIS is fully and efficiently implemented in 5 and partially in 4 countries.

As the organisational interoperability also deals with meeting the requirements of the user community, last question in this section is related to user experience. Five countries reported their IIS having clear and easy-to-follow use instructions, one partially, and for one it is N/A.

The answers are given in the table 11 below.

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Table 10 Organisational interoperability aspects: definitions, functions, alignment and integration

Country	IIS functions implementation	Alignment of business processes	IIS is integrated with population registry	IIS integration with health outcome registries	IIS is integration linked with other databases	IT infrastructure support	Use instructions
Austria	Yes	Yes	N/A	No	N/A	Yes	Yes
Belgium (Flanders)	Yes	Yes	Yes	No	No	Yes	Yes
Croatia	Partially	Partially	No	No	No	Yes	Yes
Denmark	Partially	Partially	Yes	Partially	Partially	Yes	Yes
Finland	Yes	Partially	Yes	Yes	Yes	Partially	Partially
France	Partially	Partially	Yes	Partially	Partially	Yes	Yes
Norway	Yes	Partially	Yes	No	No	Partially	Yes
Slovenia	Yes	Yes	Partially	Yes	Yes	Partially	Yes
Spain	Partially	Partially	Partially	Yes	No	N/A	N/A
Sweden	Yes	Partially	Partially	No	No	Partially	Yes

Semantic and technical interoperability

All 10 countries have reached an agreement on the core data set of information to be collected. In defining the core data set of information, international standards were consulted and implemented in IIS in 5 countries, partially in 3 countries, and two countries responded N/A on this question.

Nine (9) countries reported they have consulted the international standards when defining vocabularies and schemes (e.g., procedures, vaccines, manufacturers, ICD, adverse events) , of which partially in 3. One (1) country answered N/A to this question. In defining the information specifications (syntactic aspect of semantic interoperability), such as agreements on exact format of information, machine readability and the use of non-proprietary software, international standards were again reported as consulted in 9 countries, of which partially in 6 countries. One (1) country answered N/A to this question.

Eight (8) countries replied N/A on the question on dealing fragmented solutions developed solely for domain-specific challenges, so-called “ICT islands“(4); pointing to either the obscurity of the formulation of this question, or to the conclusion there were no such solutions in the first place.

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Table 11 Semantic and technical interoperability

Country	Agreement on data set of information to be collected	The core data set of information was defined using international standards (IS)	IS were used in defining the information vocabularies and schemes	IS were used in defining the information specifications	In the IIS implementation, ICT islands were recognized and targeted.
Austria	Yes	Yes	Yes	Yes	N/A
Belgium (Flanders)	Yes	Partially	Partially	Partially	N/A
Croatia	Yes	Yes	Partially	Partially	Partially
Denmark	Yes	N/A	Yes	No	N/A
Finland	Yes	Yes	Partially	Partially	N/A
France	Yes	Partially	Partially	Partially	N/A
Norway	Yes	Partially	Partially	Partially	N/A
Slovenia	Yes	Yes	Yes	Yes	Yes
Spain	Yes	Yes	Yes	Yes	N/A
Sweden	Yes	N/A	N/A	Partially	N/A

Additional country information

In the open-ended question section, we wanted to obtain more detailed information about those topics which have been shown to be unsuitable for more structured types of questions and answers. The questions dealt with a variety of topics, such as legal, operational and technical barriers pertaining to data sharing and data protection; quality, completeness and consistency control of data; relationship of users with IIS, including training, information literacy and available time; and perhaps most importantly, COVID-19 impact on IIS development. The countries answers are given below.

Austria

Dealing with data sharing and data protection

Users of the IIS must be authorized to have access to data stored in the ISS. The protection of data is managed through law and through compliance with the privacy rules and regulations. Each time a user is accessing the data of an individual it is logged and communicated transparently to the individual through his access-portal.

Dealing with data quality

Quality of data is mainly managed through the definition of how data need to be entered in the IIS in order to be saved. Only HL7 compliant data can be saved in the IIS. Content wise, we established national recommendations on vaccine product, dose number und vaccination scheme accordance. For data clearance there is a clear process set up, to update the immunization entry if necessary.

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Readiness for use of your IIS in terms of users' willingness, training, information literacy and time

Enablers:

- connecting existing software-systems: vaccinators can work with their already used software the system automatically sends the vaccination entries to the IIS. Another enabler was that the software-connection to the IIS was paid by the state, so all software systems were updated accordingly within 1 month.
- Tablet-Solution: For all vaccinators without an existing software-infrastructure we developed an easy-to-use / user-friendly app on secure Tablets operating in a secure network for enabling vaccinators to easily report vaccines to the IIS. Trainings were offered, however were hardly needed (good UX / UI)

Barriers:

- bad/non-user-friendly implementation within decentralized software-systems
- if terminologies in software systems are manually instead of automatically

Covid-19 impact on IIS development

It strongly accelerated (IIS development)

Belgium

Dealing with data sharing and data protection

Our juridical team, DPO, programmers and operational managers work together.

Dealing with data quality

there are some controls within the system, consistency control…

Readiness for use of your IIS in terms of users' willingness, training, information literacy and time

helpdesk available, online course on the use of the system, online manuals

Covid-19 impact on IIS development

Broadened for registering of the Covid vaccines for all regions in Belgium (Vaccinnet: Flanders region and part of Brussels, e-Vax: Walloon region and part of Brussels) and possibilities for all Belgian doctors to use the system.

Croatia

Dealing with data sharing and data protection & Readiness for use of your IIS in terms of users' willingness, training, information literacy and time

Barriers are in institutional roles and responsibilities. Main facilitator is COVID pandemic and Digital COVID Certificate.

Dealing with data quality

Data validation at data entry. Regular data quality check-ups in the database.

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Covid-19 impact on IIS development
It accelerated a lot. Many IIS functions have been developed in order to satisfy DCC standards.

Denmark

Dealing with data sharing and data protection
Sharing data in relation to external research needs an application and permission from relevant parties. If SSI is asked for specific data but there are doubts as to whether it can be handed over, the local legal department is involved.

Covid-19 impact on IIS development
It accelerated the functionalities in IIS system, digital personal identifiers (CPR) for people coming outside of Denmark and normally not having a CPR, we developed a functionality that supported registration of off label vaccinations as an integrated part of DDV.
DDV was used partly to control the gradually invitation of COVID19 to specific population groups.
The pandemic made it clear for the institute that finding risk groups is necessary to improve the vaccination coverage and reach out to the groups with the highest risk of a disease. We work on how to implement this development.

Finland

Data sharing and data protection
As much data as possible published as Open data using statistical disclosure process to assess data protection.

Dealing with data quality
Automated summaries and checks, manual checks and public reporting.

Readiness for use of your IIS in terms of users' willingness, training, information literacy and time
Immunisation information recording is an integral part of all health care services.

Covid-19 impact on IIS development
Accelerated implementation of data collection among further providers and adherence to national data collection for vaccine certificate use.

Norway

Data sharing and data protection
For legal, operational or technical barriers, internal teams will be consulted according to well defined and established GDPR routines and procedures at NIPH.
In case of a legal barrier, we consult the internal juridical department at NIPH for advice.

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Whenever there is a need for changes in the legislation, MoH is in charge.

Dealing with data quality
There are well established procedures for quality assurance of data.

Readiness for use of your IIS in terms of users' willingness, training, information literacy and time
Information about the Norwegian IIS is given in webinars, meetings etc. In addition, information and users' guidelines are published at our webpage. User support is also given via e-mail correspondence and telephone.

Covid-19 impact on IIS development
During the COVID-19 pandemic, several new needs have been identified with regards to data collections (data in) and integration of data with other registries/databases, as well as the need for daily presentation of different statistics (data out).

Slovenia

Dealing with data sharing and data protection
Issues with GDPR: Vaccinators need to provide a secure connection to share data - this is sometimes a challenge and not all providers are sharing data within IIS yet.

Dealing with data quality
Comparing vaccination coverage assessments from IIS with assessments from previous data collection system.

Readiness for use of your IIS in terms of users' willingness, training, information literacy and time
It is mandatory for vaccinators to report to IIS, but not all are connected yet due to barriers mentioned above.

Covid-19 impact on IIS development
COVID-19 accelerated development of our IIS; many more vaccinators were connected to the IIS in the last two years. We centralized the collection of vaccination data, testing data and contact tracing data...

Spain

Dealing with data sharing and data protection
We have clear and defined roles, responsibilities and rights on data ownership, an on how data is processed and used.
In addition, we have established mechanisms that ensure the law on protection of personal data is warranted.

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Our main challenge is the heterogeneity of the regional IIS currently in place, however one facilitator we have is that the data will already be pseudonymised when entered in the national IIS. This is how it is currently in the national immunisation information system specific for COVID-19 vaccination coverage (REGVACU).

Dealing with data quality

Some of the fields will be mandatory and there will be validation rules for some of them. Definition of these rules and for which fields these will apply is currently under development.

Readiness for use of your IIS in terms of users' willingness, training, information literacy and time

Since the specific IIS for COVID-19 vaccination coverage (REGVACU) was launched at the end of 2020, there has been an increasing willingness from different stakeholders to develop a national IIS for vaccine coverage of the vaccines included in the routine immunisation schedule of Spain.
The project was launched in February 2022 and it is currently in a very early stage. The national IIS is going to be as similar as possible to REGVACU therefore users will already be used to the IIS.

Covid-19 impact on IIS development

COVID -19 pandemic has had a crucial impact the development of a unique IIS for vaccine coverage of the vaccines included in the routine immunization schedule of Spain.
Spain has a decentralised healthcare system and each region has an IIS. However, at the end of 2020 a unique national IIS specific for COVID-19 vaccination coverage (REGVACU) was set up and receives daily data from the vaccines administered and registered in the different regional information systems. This IIS for COVID-19 vaccines was set up in only few months and has accelerated the development of a national IIS for all vaccines included in the immunization schedule in Spain.
In February 2022, an agreement was reached to develop a national IIS, flexible and interoperable with the current regional IIS.

Additional information

Please refer to out answer of question 4 (Covid-19 impact on IIS development). In addition, we answered N/A in some of the questions of section 6 (IIS interoperability compliance) cause the planned IIS is currently in a very early stage of development and most of the specific items referred in these questions have not been developed yet.

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Discussion

This report presents the results of the task 5.1 of the EU Joint Action on Vaccination (EU-JAV) Work package 5 in assessing the interoperability of European Immunisation Information Systems (IIS) and opportunities for standardisation. It provides an information on the status of IIS implementation in 17 European countries (Austria, Belgium (Flanders part), Bulgaria, Croatia, Denmark, France, Finland, Greece, Italy, Latvia, Lithuania, Netherlands, Norway, Slovakia, Slovenia, Spain and Sweden), IIS specifications and core functionalities, data collection, and compliance of national IIS with European interoperability framework. The possibilities on achieving international interoperability of national IIS' are discussed based on the collected information on national level.

The main prerequisite for enabling data sharing among the systems is the existence of such systems. Majority of the countries covered by this report have functional IIS or IIS in pilot phase: in March 2022, 10 countries have functional IIS, out of them 8 are national IIS and 2 are subnational; and 2 national IIS are in pilot phase (Italy and France). For 5 countries that reported not having an IIS in 2019, since we have not received from them the updated 2022 questionnaire, we are treating them in this report as being without IIS.

Regarding the level of IIS use, seven countries can provide both information at the individual level and population level, while the three can provide information only at the population level. As we aim to obtain information on possible cooperation relevant to increasing vaccine surveillance capabilities and vaccination coverage information, the individual level is of less importance for this task.

Given the requisite features of IIS for monitoring immunisation by ECDC, we analysed the set of common IIS system functionalities and characteristics. These include having complete, accurate and reliable information on 1) the denominator population, 2) identification of individual recipients, 3) vaccine data by means of limiting manual entry, 3) increasing interoperability with other databases and health registries (2). These characteristics and functionalities can act as a set of points through which the possibility for international interoperability can be assessed.

Firstly, linkage with the population or national health insurance registries is only found in some countries. Other countries are using national statistics office's estimates. While such alternatives contribute to establishing IIS in some countries, they are less liable. An integration of an IIS with the population registries contributes not only to the completeness and accuracy of the data at national, but also at the international level, ensuring the possibilities for standardisation.

Secondly, all of the countries with an either operational or pilot-phase IIS do have a secure vaccine recipient and record identification through uniform unique identifiers (UID), which enables unique identification of immunisations recipients.

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Thirdly, both countries with and without IIS do have records of vaccinations records and vaccine details records (batch and vial ID etc.) given to the recipients, including the dates of doses. Along with the UID, these records constitute the minimal structured data architecture for an IIS to be built upon. Furthermore, this foundational architecture is necessary for an EU wide data sharing and exchange.

Fourthly, fully digitalised timely data collection, enabling monitoring of public health issues, is a major contribution of IIS. However, timely data collecting remains a problem for countries without IIS. Ability to enter past vaccination records, including vaccinations administered in other countries of regions, is a significant improvement already existing in many countries.

Among the existing barriers for improving international data exchange and sharing, legislations regarding the mandatory data collection on vaccination stand out. Some countries lack any sort of such legislations, while in others it is mandatory to collect only some vaccination data, such as age (childhood vaccinations) or type, e.g., influenza or COVID-19. Other important aspect that differs across countries is whether private providers are covered as much as the public ones.

Fifthly, in the majority of countries with an IIS, governance of interoperability processes, as well governance and ownership over IIS, are fully or partially established, with high-level political support existing in most countries. Full or partially continued financial and resources support exist in all the countries apart from France, with the future planning existing in all the countries other than Slovenia. The responses from the stakeholders have shown that all four levels of interoperability are addressed in each of the countries to a various extent. It is worth highlighting that on the level of semantic and technical interoperability, all the countries have reached an agreement on the specification on the data set of information to be collected, all with the extensive use of informational standards.

Overall, all of the above indicates that there are significant foundational elements in place in most national public health systems for the data sharing and exchange to be established among the countries' systems.

As to the important matter of international interoperability, the results point to the fact that all the countries have the experience with dealing with interoperability nationally on all mentioned layers of the interoperability. However, the COVID-19 pandemic has demonstrated in practice that given the significant public outcry and the highest level national and international political and scientific support, complex, interoperable public health systems with many of the desires features discusses in this report, can be achieved in relative short periods of time. This achievement can be broadened to the closely integration of other aspects of IIS, internationally.

The study has some significant limitations. Many EU/EEA countries are excluded as the study covers the 17 countries only. The second major limitation has been methodological, imposed by the pandemic, as it has severely limited the resources available for the study. This is especially prominent in the lack of direct interviews with the respondents, which we believe would have greatly enhanced our insights and knowledge about many of the topics covered in the questionnaire. Furthermore, it

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limited the opportunity to perform the thorough analysis of the major changes in IIS development brough by the pandemic and bring more information about the aspects of international integration. Regardless, significant conclusions towards European wide public health action can be inferred from the study.

To conclude, majority of the countries covered by this report have either functional IIS or IIS in piloting phase.

The answers obtained on IIS specifications, functionalities and data collection point out that, despite the great diversity among existing systems, there the prerequisites for establishing the interoperability on international level for those countries are already present.

However, in order to achieve full international interoperability of national IIS, there are several key steps that need to be taken. Firstly, countries without an IIS need to accelerate their IIS development. Secondly, a holistic governance that would take into account the workflow, human and financial resources and sustainability needs to be established on the EU/international level. And finally, as we learned from the EU/EEA answer to COVID-19 pandemic, the highest level of political support is of a fundamental importance for interoperability facilitation.

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Appendices

Appendix 1: Survey on Interoperability of Immunisation Information Systems (IIS)

Dear Colleagues,

As a part of EU-JAV project Work package 5, we are launching a survey on electronic Immunisation Information Systems (IIS) in the EU and other non-member states. IIS is any electronic system that records vaccinations at the individual level. The term IIS hence encompasses terms such as Electronic Immunisation Records, and includes electronic systems that allow aggregation of individual-based records for monitoring of the vaccination programme (e.g., monitoring of vaccination coverage). Some EU Member States have national systems, others have one or more than one regional or provincial systems that may or may not allow exchange of data with each other. Others still have not yet established IIS.

EU-JAV aims to strengthen cooperation between European countries to fight vaccine-preventable diseases. The final goal of Work package 5 is to strengthen the interaction of Immunization Information Systems (IIS) in Europe in order to increase vaccine surveillance capabilities and to increase vaccination coverage.

The first step in reaching the goals of the project is to identify how interoperable different European IIS systems are, and that is the purpose of this survey.

Several questions in this survey are similar to the questions asked by ECDC in their survey (Immunisation Information Systems Survey (IIS)-EU/EEA from May 2016, and are asked again in order to have an update on the development of the IIS in your country/region.

This survey can be revisited several times before being submitted and doesn't require the respondent to have all information at hand in one session.

The survey may be followed up by an interview.

We would appreciate responding to this survey no later than _____.

This survey has been approved by _____.

For further contact(questions) on the survey, even while completing, please do not hesitate to contact _____.

We thank you in advance for your participation and for the time you will spend on it. It is expected to take approximately 30 minutes to respond according to the specific situation in your country.

1 Respondent information (A)

1.1 Please indicate your name:
1.2 Please indicate your e-mail
1.3 Please indicate your telephone number:
1.4 Please indicate your country
1.5 Please indicate region if applicable:

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2 General information (B)

In this section we would like you to indicate current situation on recording vaccination data in your country

2.1 Please indicate the option that best describes vaccination records in your country(6):
- a) A national IIS is operational (GO TO 2.6)
- b) A national IIS is currently being piloted (GO TO 2.6)
- c) One sub-national IIS is operational (GO TO 2.5)
- d) More than one sub-national IISs are operational (GO TO 2.2)
- e) One sub-national IIS is currently being piloted (GO TO 2.5)
- f) More than one sub-national IISs are currently being piloted (GO TO 2.2)
- g) No IIS implemented (GO TO AM1.1)

2.2 If more than one sub-national IISs are operational, please further specify if(6):
- a) They have **similar structures**, characteristics or data elements and **data can be shared among systems**
- b) They have **different structures**, characteristics or data elements, but **data can be shared among systems**
- c) They have different structures, characteristics or data elements and **data sharing among systems is not possible**

2.3 If more than one sub-national IISs are operational in your country, please indicate the number of existing systems(6)

2.4 If more than one sub-national IISs are operational in your country, please indicate for each of them the approximate size of the population living in the areas covered by the systems(6)

2.5 If possible, please mention which geographical areas are covered by the sub-national system/systems, using the NUTS classification (see this link for NUTS class.) (6)

2.6 If you have any additional comments that you would like to share to better understand the situation in your country, please write them here(6)

3 Description of IIS (C)

This section will explore the national IIS or, if a national system is not in place in your country, the sub-national IIS you are describing. All the following questions are referring to the system you are describing.

This section is also applicable for systems at national or sub-national level that are currently being piloted and should reflect plans foreseen.

3.1 Please indicate the name of the IIS(6)

3.2 Is it a national system? (6)
- a) Yes (GO TO 3.5)
- b) No, it is a sub-national system (GO TO 3.3)

3.3 If sub-national, please approximatively indicate the approximate size of the of the population living in the areas covered by the systems(6)

3.4 If sub-national, please indicate which area is covered by the IIS, using the NUTS classification(6)

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3.5 Does the description of your IIS fits with the following definition of an IIS? (6)
Immunization information systems (IIS) are confidential, population-based, computerized databases that record all immunization doses administered by participating providers to persons residing within a given geopolitical area. At the point of clinical care, an IIS can provide consolidated immunization histories for use by a vaccination provider in determining appropriate client vaccinations. At the population level, an IIS provides aggregate data on vaccinations for use in surveillance and program operations, and in guiding public health action with the goals of improving vaccination rates and reducing vaccine-preventable disease (According to CDC)
   a) Yes (GO TO 3.7)
   b) No (GO TO 3.6)

3.6 If no, please specify the definition that would best describe your system(6)

3.7 In what year was the IIS first established in routine use? [or year of planned implementation for systems being piloted] (6)

3.8 Which organisation or institution holds the governance for the IIS? Multiple answers possible(6)
   a) National Institute of Public Health (or equivalent)
   b) Regional Institute of Public Health (or equivalent)
   c) Ministry of Health
   d) Regional Health Authorities
   e) National health insurance organisation
   f) Other:

3.9 If other, please specify(6)

3.10 Are **public** vaccination providers required by law or regulations to record individual vaccinations in the IIS? (6)
   a) Yes (GO TO 3.11)
   b) No (GO TO 3.12)

3.11 Please choose which **public** vaccines registration is required by law:
   a) Vaccinations given in childhood vaccination programme
   b) Vaccinations given in other programmes (e.g., Influenza vaccines)
   c) All vaccinations

3.12 Are **private** vaccination providers required by law or regulations to record individual vaccinations in the IIS? (6)
   a) Yes
   b) No

3.13 Please choose which **private** vaccines registration is required by law:
   a) Vaccinations given in childhood vaccination programme
   b) Vaccinations given in other programmes (e.g., Influenza vaccines)
   c) All vaccinations

3.14 If you have any additional comments that you would like to share to better understand the situation in your country, please write them here: (6)

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4 Characteristics of the system (D)

This section of the questionnaire will explore the population that is covered by the IIS and how individuals included in the register are identified.

4.1 **All** vaccinations provided (regardless of recommendations, age, risk factors etc..) are recorded in the IIS(6)
- a) Yes
- b) No

4.2 Childhood vaccinations included in the national/regional immunisation programmes are recorded in the IIS(6)
- a) Yes
- b) No

4.3 Adolescents vaccinations included in the national/regional immunisation programmes are recorded in the IIS. (6)
- a) Yes
- b) No

4.4 Adults vaccinations included in the national/regional immunisation programmes are recorded in the IIS. (6)
- a) Yes
- b) No

4.5 Vaccinations included in the recommended school-based vaccination programme are recorded in the IIS. (6)
- a) Yes
- b) No
- c) Not applicable

4.6 Is each immunised individual, recorded in the IIS, identified with a unique identifier? (6)
- a) Yes (GO TO 4.8)
- b) No (GO TO 4.7)
- c) I do not know

4.7 If No, please describe how each immunised individual is identified in the database (GO TO 4.9)(6)

4.8 How is the unique personal identifier generated? (6)
- a) The IIS uses the unique identifier given to citizens at birth or immigration
- b) The IIS uses the unique identifier used for healthcare services
- c) The IIS uses a unique identifier specific for the immunisation registry
- d) Other

4.9 If other, please specify(6):

4.10 What is the minimal set of data variables to be recorded for an immunisation record to be valid (please list) (6)?

4.11 Can vaccinations administered in the past be recorded in the IIS? (6)
- a) Yes
- b) No

4.12 Can vaccinations administered in a foreign country be recorded? (6)
- a) Yes

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b) No

4.13 In case of sub-national systems, can vaccinations administered in another region be recorded? (6)

a) Yes
b) No
c) Not applicable

4.14 How is the data that identifies the vaccine administered recorded? One answer possible. (6)

a) Manually
b) Electronically with the help of a bar code reader
c) By selecting from a list of vaccines included in the registry
d) By linking to a product database
e) Other (specify)

4.15 If other, please select(6)

4.16 How are vaccinations recorded in IIS? Multiple answers possible

a) Vaccinations recorded by trade name
b) Vaccinations recorded by local coding (GO TO 4.17)
c) Vaccinations recorded by batch/lot number
d) ATC classification
e) By antigen
f) Other:

4.17 Are the local codes uniform for the whole country or can they differ between regions?

a) Yes, they are uniform
b) No, codes differ (GO TO 4.18)

4.18 Please, specify how codes differ:

4.19 Please specify who is responsible for the coding system:

a) Country medicinal authority (or equivalent)
b) Regional medicinal authority (or equivalent)
c) Ministry of Health (or equivalent)
d) Health Insurance Fund (or equivalent)
e) Public Health Institution (or equivalent)
f) Other:

4.20 Is dose number recorded (e.g. D1 as Dose 1, D2 as Dose2 etc.)

a) Yes
b) No (GO TO 4.21)

4.21 Please, specify how are measles containing doses identified:

4.22 Do you have access to vaccination data on regional/country level?

a) Yes
b) No

4.23 Will you be able to prepare a vaccination file including all measles containing vaccine doses (e.g. D1 and D2) administered to children belonging to the birth cohorts 2005 - 2019 including the following core variables per vaccine dose per PersonID (Please see data example in Annex 1

Variable name	Can prepare	Cannot prepare	Not applicable

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PersonID			
Date			
Vacname			
Vactype			
ATC			
Dose			

Annex 1

Variable name	Meaning	Format
PersonID	Person Identifier	
Date	Date of administration	Format YYYYMMDD.
Vactype	Type of vaccine (antigens)	Three letter code per antigen (Mea-Mum-Rub-Var)
ATC	Type of vaccine	ATC code, 7 digits.
Dose	Dose received as specified in database or determined by the database custodian based on knowledge of the local immunization schedule	
	possible values	Description
	D1	For first dose
	D2	For second dose

4.24 Is measles containing vaccine information available for all 15 birth cohorts (2005-2019)?

a) Yes

b) No (GO TO 4.25)

4.25 Please, specify for which birth cohorts can you prepare a vaccination file:

4.26 If you have any additional comments that you would like to share to better understand the situation in your country, please write them here(6)

4a Characteristics of the system (DA)

This section of the questionnaire will explore the population that is covered by the IIS and how individuals included in the register are identified.

Please answer for both currently operating system and the system being piloted.

For systems being piloted, please indicate the population that is planned to be included in the system.

DA4.1 **All** vaccinations provided (regardless of recommendations, age, risk factors etc..) are recorded. (6)

	Current system	IIS being piloted
Yes	1	1

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No	2	2

DA4.2 Childhood vaccinations included in the national/regional immunisation programmes are recorded. (6)

	Current system	IIS being piloted
Yes	1	1
No	2	2

DA4.3 Adolescents vaccinations included in the national/regional immunisation programmes are recorded. (6)

	Current system	IIS being piloted
Yes	1	1
No	2	2

DA4.4 Adults vaccinations included in the national/regional immunisation programmes are recorded. (6)

	Current system	IIS being piloted
Yes	1	1
No	2	2

DA4.5 Vaccinations included in the recommended school-based vaccination programme are recorded. (6)

	Current system	IIS being piloted
Yes	1	1
No	2	2
Not applicable	3	3

DA4.6 Is each immunised individual, recorded in the current system, identified with a unique identifier? (6)

a) Yes (GO TO DA4.7)
b) No (GO TO DA4.8)
c) I do not know

DA4.7 How is the current systems' unique personal identifier generated? (6)

a) The IIS uses the unique identifier given to citizens at birth or immigration
b) The IIS uses the unique identifier used for healthcare services
c) The IIS uses a unique identifier specific for the immunisation registry
d) Other

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DA4.8 If No, please describe how each immunised individual is identified in the current system database (6)

DA4.9 Is each immunised individual, recorded in the piloted IIS, identified with a unique identifier? (6)

a) Yes (GO TO DA4.10)
b) No (GO TO 4.11)
c) I do not know

DA4.10 How is the piloted IIS unique personal identifier generated? (6)

a) The IIS uses the unique identifier given to citizens at birth or immigration
b) The IIS uses the unique identifier used for healthcare services
c) The IIS uses a unique identifier specific for the immunisation registry
d) Other

DA4.11 If No, please describe how each immunised individual is identified in the IIS being piloted database (6)

DA4.12 Please indicate for the current system - what is the minimal set of data variables to be recorded for an immunisation record to be valid (please list) (6)?

DA4.13 Please indicate for the IIS being piloted - what is the minimal set of data variables to be recorded for an immunisation record to be valid (please list) (6)?

DA4.14 Can vaccinations administered in the past be recorded in the IIS? (6)

	Current system	IIS being piloted
Yes	1	1
No	2	2

DA4.15 Can vaccinations administered in a foreign country be recorded? (6)

	Current system	IIS being piloted
Yes	1	1
No	2	2

DA4.16 In case of sub-national systems, can vaccinations administered in another region be recorded? (6)

	Current system	IIS being piloted
Yes	1	1
No	2	2
Not applicable	3	3

DA4.17 Please indicate for the current system - how is the data that identifies the vaccine administered recorded? One answer possible. (6)

a) Manually
b) Electronically with the help of a bar code reader

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c) By selecting from a list of vaccines included in the registry
d) By linking to a product database
e) Other (specify)

DA4.18 Please indicate for the IIS being piloted - how is the data that identifies the vaccine administered recorded? One answer possible. (6)

a) Manually
b) Electronically with the help of a bar code reader
c) By selecting from a list of vaccines included in the registry
d) By linking to a product database
e) Other (specify)

DA4.19 How are vaccinations recorded in the current system? Multiple answers possible

a) Vaccinations recorded by trade name
b) Vaccinations recorded by local coding (GO TO DA4.20)
c) Vaccinations recorded by batch/lot number
d) ATC classification
e) By antigen
f) Other:

DA4.20 Please indicate for the current system - are the local codes uniform for the whole country or can they differ between regions?

a) Yes, they are uniform
b) No, codes differ (GO TO DA4.21)

DA4.21 Please, specify how codes differ:

DA4.22 How are vaccinations recorded in the IIS being piloted? Multiple answers possible

a) Vaccinations recorded by trade name
b) Vaccinations recorded by local coding (GO TO DA4.23)
c) Vaccinations recorded by batch/lot number
d) ATC classification
e) By antigen
f) Other:

DA4.23 Please indicate for the current system - are the local codes uniform for the whole country or can they differ between regions?

a) Yes, they are uniform
b) No, codes differ (GO TO DA4.24)

DA4.24 Please, specify how codes differ:

DA4.25 For the current system - please specify who is responsible for the coding system:

a) Country medicinal authority (or equivalent)
b) Regional medicinal authority (or equivalent)
c) Ministry of Health (or equivalent)
d) Health Insurance Fund (or equivalent)
e) Public Health Institution (or equivalent)
f) Other:

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DA4.26 For the IIS being piloted - please specify who is responsible for the coding system:

a) Country medicinal authority (or equivalent)
b) Regional medicinal authority (or equivalent)
c) Ministry of Health (or equivalent)
d) Health Insurance Fund (or equivalent)
e) Public Health Institution (or equivalent)
f) Other:

DA4.27 For the current system - is dose number recorded (e.g., D1 as Dose 1, D2 as Dose2 etc.)

a) Yes
b) No (GO TO DA4.28)

DA4.28 For the current system - please, specify how are measles containing doses identified:

DA4.29 For the IIS being piloted - is dose number recorded (e.g., D1 as Dose 1, D2 as Dose2 etc.)

a) Yes
b) No (GO TO DA4.30)

DA4.30 For the IIS being piloted - please, specify how are measles containing doses identified:

DA4.31 Do you have access to vaccination data on regional/country level?

	Current system	IIS being piloted
Yes	1	1
No	2	2

DA4.32 Will you be able to prepare a vaccination file including all measles containing vaccine doses (e.g. D1 and D2) administered to children belonging to the birth cohorts 2005 - 2019 including the following core variables per vaccine dose per PersonID (Please see data example in Annex 1

Variable name	Can prepare	Cannot prepare	Not applicable
PersonID			
Date			
Vacname			
Vactype			
ATC			
Dose			

Annex 1

Variable name	Meaning	Format
PersonID	Person Identifier	
Date	Date of administration	Format YYYYMMDD.
Vactype	Type of vaccine (antigens)	Three letter code per antigen (Mea-Mum-Rub-Var)

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ATC	Type of vaccine	ATC code, 7 digits.
Dose	Dose received as specified in database or determined by the database custodian based on knowledge of the local immunization schedule	
	possible values	Description
	D1	For first dose
	D2	For second dose

DA4.33 Is measles containing vaccine information available for all 15 birth cohorts (2005-2019)?,

a) Yes
b) No (GO TO DA4.34)

DA4.34 Please, specify for which birth cohorts can you prepare a vaccination file:

DA4.35 If you have any additional comments that you would like to share to better understand the situation in your country, please write them here(6)

5 Input (E)

This section will explore in detail the links established between the IIS and other registries in your country or region including civil registries and other health-related registries.

5.1 Is information included in the IIS fed by any population registry? Multiple answers possible. (6)
a) No, data are entered manually only at time of a person encounter for immunisation
b) Yes, by civil population registries
c) Yes, by healthcare population registries
d) Other (specify)

5.2 Is an individual vaccination record set-up automatically in the IIS at the time of the registration of a live birth (or a certain time later)? (6):
a) Yes
b) No

5.3 Is an individual vaccination record set-up automatically in the IIS at the time of immigration (or a certain time later)? (6):
Yes
No

5.4 What is the estimated time between vaccination and the information being entered into the IIS? (Only one response possible) (ECDC, 2017)
a) Data are entered at the time of vaccine administration
b) Within 1 day
c) Within 1 week (7 days)
d) Within 2 weeks
e) Within 1 month
f) 1-3 months
g) Other, specify (e.g., estimated time not mentioned above; depending on vaccination or method used or sub-national area, etc…)

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5.5 If you have any additional comments that you would like to share to better understand the situation in your country, please write them here (ECDC, 2017):

5a Input (EA)

This section will explore in detail the links established between the IIS and other registries in your country or region including civil registries and other health-related registries.

Please answer for both currently operating system and the system being piloted. For systems being piloted, please indicate the plans foreseen.

EA1. Is information included in the current system fed by any population registry? Multiple answers possible. (6)

a) No, data are entered manually only at time of a person encounter for immunisation
b) Yes, by civil population registries
c) Yes, by healthcare population registries
d) Other (specify)

EA2. Is information included in the IIS fed by any population registry? Multiple answers possible. (6)

a) No, data are entered manually only at time of a person encounter for immunisation
b) Yes, by civil population registries
c) Yes, by healthcare population registries
d) Other (specify)

EA3. Is an individual vaccination record set-up automatically in the IIS at the time of the registration of a live birth (or a certain time later)? (6):

	Current system	IIS being piloted
Yes	1	1
No	2	2

EA4. Is an individual vaccination record set-up automatically in the IIS at the time of immigration (or a certain time later)? (6):

	Current system	IIS being piloted
Yes	1	1
No	2	2

EA5. What is the estimated time between vaccination and the information being entered into the current system? (only one response possible) (ECDC, 2017)

a) Data are entered at the time of vaccine administration
b) Within 1 day
c) Within 1 week (7 days)
d) Within 2 weeks
e) Within 1 month
f) 1-3 months

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g) Other, specify (e.g., estimated time not mentioned above; depending on vaccination or method used or sub-national area, etc…)

EA6. What is the estimated time between vaccination and the information being entered into the IIS being piloted? (Only one response possible) (ECDC, 2017)

a) Data are entered at the time of vaccine administration
b) Within 1 day
c) Within 1 week (7 days)
d) Within 2 weeks
e) Within 1 month
f) 1-3 months
g) Other, specify (e.g. estimated time not mentioned above; depending on vaccination or method used or sub-national area, etc…)

EA7. If you have any additional comments that you would like to share to better understand the situation in your country, please write them here (ECDC, 2017):

6 Denominator calculation (F)

6.1 What is the smallest administrative area for which you can compute aggregated vaccination uptake/coverage? (only one response possible) (ECDC, 2017)

a) NUTS 1
b) NUTS 2
c) NUTS 3
d) Other than listed above (GO TO 6.2)
e) It is not possible to calculate vaccination uptake/coverage (GO TO 6.3)

6.2 Please, specify the smallest administrative area for which you can compute aggregated vaccination uptake/coverage:

6.3 Please, specify why is it not possible to calculate vaccination uptake/coverage:

6.4 What are the sources of denominator data for the IIS? (ECDC, 2017)

a) Civil population registries
b) Healthcare population registries
c) Other than listed above, please specify:

6.5 What is the delay between birth and immigration and registration in population register:

a) Within 1 day
b) Up to a week
c) Up to a month
d) Other, please specify:

6.6 What is the delay between death and emigration and exit from the population register:

a) Within 1 day

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b) Up to a week
c) Up to a month
d) Other, please specify:

6.7 Do you have access to population data at regional/country level?
a) Yes
b) No

6.8 Will you be able to prepare a population file containing all individuals from the birth cohorts 2005- 2019 including the following core variables per PersonID:

Variable name	Can prepare	Cannot prepare	Not applicable
PersonID			
Birthdate			
Gender			
NUTS ID			
Startdate			
Enddate			

Annex 2

Variable name	Meaning	Format
PersonID	Person Identifier	Unique
Birthdate	Date of birth	YYYYMMDD
Gender	Gender	F for Female M for Male
NUTS ID	NUTs identification e.g DK050, DK041, DK042….	
Startdate	Date from which the person is registered in the registration system (date of birth, date of immigration).	YYYYMMDD

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Enddate	Date after which the person is no longer registered in the registration system (e.g death or emigration)	YYYYMMDD

6.9 Are you allowed to prepare the proposed vaccination and populations files?
- a) Yes
- b) No

6.10 Are **you** allowed to estimate MMR1 and MMR2 coverage based on the algorithm developed and shared and upload the regional coverage estimates to a common platform?
- a) Yes
- b) No

6.11 Are we allowed to show regional coverage estimates that you provide on a common platform?
- a) Yes
- b) No

6.12 How often would be feasible to extract data?
- a) Daily
- b) Weekly
- c) Monthly
- d) Biannually
- e) Annually

6.13 If you have any additional comments that you would like to share to better understand the situation in your country, please write them here (ECDC, 2017)

7 Challenges and barriers (G)

This section will explore challenges that may have been faced at various stages of the implementation of the IIS. We are listed common challenges and would like to explore to what extent they had an impact on developments in your country.

7.1 For each of the following factors, please indicate how much they represented a challenge to be overcome **before** a decision was taken to set up the IIS or before a decision was taken to pilot an IIS. (ECDC, 2017)

	Yes	Somewhat	No
1.Need to vote a legislation to govern the use of the IIS	1	2	3

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2.Need to establish governance and ownership (defining who was in charge of responsibility of the system)	1	2	3
3.Data protection issues	1	2	3
4.Lack of funding	1	2	3
5.Lack of human resources	1	2	3
6.Definition of users and stakeholders to be involved	1	2	3
7.Decentralisation of immunisation programmes	1	2	3
8.Lack of efficient infrastructure that could support the IIS (e.g. lack of computer or Internet connection at the local level)	1	2	3
9. Low information literacy	1	2	3

7.2 If you met other relevant challenges (not mentioned above) in the decision to set up the IIS, please feel free to describe further (ECDC, 2017):

7.3 For each of the following factors, please indicate how much they represented a challenge to be overcome during the design phase of the IIS (ECDC, 2017)

	Yes	Somewhat	No
1.Expanding the existing infrastructure/lack of efficient infrastructure (e.g. lack of computer or Internet connection at the local level)	1	2	3
2.Lack of standards as point of reference for developing the system	1	2	3
3.Defining the functions required by the systems	1	2	3
4.Defining the core data set of information to be collected	1	2	3
5.Defining rules for access rights to different users (national agency, local health officers, health providers…)	1	2	3
6.Defining rules for data sharing among different users (national agency, local health officers, health providers…)	1	2	3
7.To find out how to register information on the vaccine administered	1	2	3
8.Integration with the population registries feeding the IIS	1	2	3

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9.Linkage to other health outcome registers, e.g. notifiable diseases	1	2	3
10. Low information literacy	1	2	3

7.4 If you met other relevant challenges (not mentioned above) in the decision to set up the IIS, please feel free to describe further (ECDC, 2017):

7.5 For each of the following factors, please indicate how much they represented a challenge to be overcome during the early use of the IIS [Please thick *not applicable* for systems currently being piloted] (ECDC, 2017)

	Yes	Somewhat	No	Not applicable
1.Acceptance of the system by the vaccination providers	1	2	3	4
2.Training needs of vaccine providers for using of the system	1	2	3	4
3.Timely assistance of health providers	1	2	3	4
4.Lack of efficient IT infrastructure	1	2	3	4
5.Lack of resources in term of staff working with vaccine administration	1	2	3	4
6.Quality control of data completeness	1	2	3	4
7.Quality control of data consistency	1	2	3	4
8.Validation of data entered by different users	1	2	3	4
9.Experience of errors like sending invitation to not targeted individuals (e.g. already vaccinated individuals, dead persons)	1	2	3	4
10.Experience of people not wanting to be monitored or identified through unique identification numbers	1	2	3	4
11.Entering of retrospective data	1	2	3	4
12.Difficulties to avoid data duplication	1	2	3	4
13.Importation/merge of existing vaccination data from other health data sources	1	2	3	4
14.Defining a denominator for coverage calculation	1	2	3	4
15. Low information literacy	1	2	3	4

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7.6 If you met other relevant challenges (not mentioned above) in the set-up phase of the IIS, please feel free to describe further (ECDC, 2017):

8 Comments

8.1 Please add any additional information or links to references or websites to further describe the IIS in your country (ECDC, 2017)

Vaccine coverage estimation by administrative method (No IIS)

AM1 General

AM1.1 What is the closest model of reporting vaccines administrated?

a) National
b) Sub-national without sharing on national level
c) Sub-national with sharing on national level
d) Other:

AM1.2 How is data for vaccination reported?

a) Type of vaccination by general name (MMR, Influenza, HPV etc.)
b) By dose
c) ATC codes
d) Other:

AM1.3 How often do you receive administrative data?

a) Once a week
b) Twice a month
c) Monthly
d) Quarterly (year)
e) Other:

AM1.4 What are the sources of denominator data when estimating coverage? (ECDC, 2017)

a) Civil population registries
b) Healthcare population registries
c) Population estimation made by relevant authority (statistics bureau or equivalent)
d) Other:

AM1.5 Which organisation or institution is responsible for vaccination coverage estimates? Multiple answers possible(6)

g) National Institute of Public Health (or equivalent)
h) Regional Institute of Public Health (or equivalent)
i) Ministry of Health
j) Regional Health Authorities
k) National health insurance organisation
l) Other:

AM1.6 How often is coverage estimated for each birth cohort?

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a) Monthly
b) Half-year
c) Yearly
d) Every second year or other frequency

AM1.7 Is coverage estimated for all MMR doses?

a) Yes
b) No

AM2 Barriers and plans for the future

AM2.1 For each of the following factors, please indicate how much they represented a barrier to the plan/implement an IIS in your country. (ECDC, 2017)

	Yes	Somewhat	No
1.Lack of funding	1	2	3
2.Lack of human resources	1	2	3
3.Need to vote a legislation to govern the use of the IIS	1	2	3
4.Need to establish governance and ownership (defining who was in charge of responsibility of the system)	1	2	3
5.Data protection issues	1	2	3
6.Definition of users and stakeholders to be involved	1	2	3
7.Decentralisation of immunisation programmes	1	2	3
8.Lack of efficient infrastructure that could support the IIS (e.g., lack of computer or Internet connection at the local level)	1	2	3
9.Lack of standards as point of reference for developing the system	1	2	3
10.Defining rules for access rights to different users (national agency, local health officers, health providers…)	1	2	3
11. Low information literacy	1	2	3

AM1.8 If you have any additional comments that you would like to share to better understand the situation in your country, please write them here(ECDC, 2017)

Annex 1

Example showing Vaccination file

PersonID	Date	Vactype	ATC	Dose
180	20060425	Mea	J07BD01	D1
180	20100127	Mea	J07BD01	D2
425	20140823	Mea-Mum-Rub	J07BD52	D1

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425	20180520	Mea-Mum-Rub	J07BD52	D2
630	20190210	Mea-Mum-Rub	J07BD52	D1

Example showing population file

PersonID	Birthdate	Gender	NUTS ID	Startdate	Enddate
180	20050119	M	DK050	20050119	20121016
425	20130519	F	DK041	20130519	20190403
630	20181204	F	DK042	20181204	20190403

Appendix 2: Survey on Interoperability of Immunisation Information Systems (IIS) follow-up

Dear Colleagues,

As a part of EU-JAV project Work package 5, we are launching a survey on electronic Immunisation Information Systems (IIS) in the EU and several other non-member states.

IIS is any electronic system that records vaccinations at the individual level. The term IIS hence encompasses terms such as Electronic Immunisation Records, and includes electronic systems that allow aggregation of individual-based records for monitoring of the vaccination programme (e.g., monitoring of vaccination coverage). Some EU Member States have national systems, others have one or more than one regional or provincial systems that may or may not allow exchange of data with each other. Others still have not yet established IIS. This survey is intended for all countries, no matter do they have operating IIS, IIS being piloted, or no IIS at all.

The final goal of Work package 5 is to strengthen the interaction of Immunization Information Systems (IIS) in Europe in order to increase vaccine surveillance capabilities and to increase vaccination coverage. The first step in reaching the goals of the project is to identify how interoperable different European IIS systems are, and that is the purpose of this survey.

European Interoperability Framework (EIF) defines interoperability as „the ability of organisations to interact towards mutually beneficial goals, involving the sharing of information and knowledge between these organisations, through the business processes they support, by means of the exchange of data between their ICT systems." (2017:5). EIF proposes an interoperability model composed of four layers of interoperability – legal, organisational, semantic and technical; a cross-cutting component of the four layers, 'integrated public service governance'; and a background layer, 'interoperability governance' – and of 12 underlying principles.

The first part of this survey is the same as the you already participated in June-August 2019, and need to be updated only if there were significant changes since then. The questions in this part are similar to the questions asked by ECDC in their survey (Immunisation Information Systems Survey

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(IIS)-EU/EEA from May 2016, and are asked again in order to have an update on the development of the IIS in your country/region.

Second part of this survey is based on new European Interoperability Framework (2017). For the purpose of this survey, we interweaved 4 layers of interoperability with the principles to gather information on the status of the implementation of your Immunisation information system.

This survey can be revisited several times before being submitted and doesn't require the respondent to have all information at hand in one session. We would appreciate responding to this survey no later than _____. If you prefer a teleconference interview instead of submitting a survey, please let us know. For further contact (questions) on the survey, even while completing, please do not hesitate to contact _____.

We thank you in advance for your participation and for your time. It is expected to take between 15 and 30 minutes to respond according to the specific situation in your country.

1 Respondent information (A)

1.1 Please indicate your name:
1.2 Please indicate your e-mail:
1.3 Please indicate your telephone number:
1.4 Please indicate your country:
1.5 Please indicate region if applicable:

If there were significant changes in your IIS since summer 2019, please answer questions from sections B, C, D and E. If there were no significant changes, skip to 6 - IIS Interoperability compliance (F)

6 IIS Interoperability compliance (F)

This section will explore the compliance of the IIS with the new *European Interoperability Framework – EIF* (2017*)*.

6.1 For each of the following factors, please indicate the level of their implementation in regard to your IIS / piloting IIS / or planned IIS:

		Yes	Partially	No	N/A
1.	There is a holistic governance of interoperability activities across administrative levels and sectors regarding IIS (frameworks, institutional arrangements, organisational structures etc.)	1	2	3	4
2.	Governance and ownership over IIS are agreed upon and established.	1	2	3	4
3.	Legislation regarding IIS suits not only the physical but also the digital world.	1	2	3	4
4.	Legislation regarding IIS successfully identifies barriers to digital exchange.	1	2	3	4

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		Yes	Partially	No	N/A
5.	Legislation regarding IIS identifies and assess its ICT impact on stakeholders.	1	2	3	4
6.	There is a high-level support (ministries, etc) regarding IIS governance and use.	1	2	3	4
7.	Continued financing of support and operations of the resources is ensured.	1	2	3	4
8.	Funding and planning of future development of the resources is ensured.	1	2	3	4
9.	Legislation regarding the availability of data from IIS is clear and easy to understand.	1	2	3	4
10.	Legislation and rules regarding the availability of data from IIS are clear and easy to understand.	1	2	3	4
11.	Users and stakeholders involved in the IIS are the outcome of the analysis of the effected parties and involved experts	1	2	3	4
12.	There are formal agreements that define access rights to different users (national agencies, health providers...)	1	2	3	4
13.	There are formal agreements that define data sharing between different users (national agencies, health providers…)	1	2	3	4
14.	National health information system is well organised (in an opposition to decentralised systems with disperse responsibility)	1	2	3	4
15.	Immunisation programmes are centralised (in an opposition to decentralised systems with disperse responsibility)	1	2	3	4
16.	Data collection is mandatory.	1	2	3	4
17.	Functions required by the systems are defined and implemented.	1	2	3	4
18.	Business processes are well integrated and aligned.	1	2	3	4
19.	IIS is integrated with population registry.	1	2	3	4
20.	IIS is integrated/linked with other health outcome registries.	1	2	3	4
21.	IIS is integrated/linked with other databases (e.g. vaccine information)	1	2	3	4
22.	IT infrastructure that supports the IIS is efficient.	1	2	3	4
23.	Instructions for using ISS are clear and easy to follow.	1	2	3	4
24.	Core data set of information to be collected is established.	1	2	3	4

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		Yes	Partially	No	N/A
25.	In defining the core data set of information, international standards were consulted and implemented.	1	2	3	4
26.	In defining the information vocabularies and schemes (procedures, vaccines, manufacturers, ICD, adverse events etc), international standards were consulted and implemented.	1	2	3	4
27.	In defining the information specifications (exact format of information, machine readable, non-proprietary), international standards and recommendations were consulted and implemented.	1	2	3	4
28.	In the IIS implementation, ICT islands (fragmented solutions developed solely for domain-specific challenges) were recognized and targeted.	1	2	3	4

7 Open questions on interoperability (G)

This is an open question section. We would very much like to hear your information on following topics regarding the interoperability of your IIS.

7.1 Data sharing and data protection issues

7.2 IIS data quality issues

7.3 Barriers in IIS use (in terms of users' willingness, training and information literacy)

7.4 COVID-19 impact on IIS development

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7.5 If you have any additional comments that are relevant for the topic, please write them here:

Thank you for your cooperation!

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